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HERBALIFE INTERNATIONAL OF AMERICA, INC.
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JOHN P. VENARDOS
Vice President, Regulatory Affairs
International Product Management

4451 '99 APR -7 19:53

December 30, 1998

1/5/99

Office of Special Nutritionals (HFS-450)
Center For Food Safety and Applied Nutrition
FOOD & DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

Ref.: **Woman's Choice Dietary Supplement**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. is commercializing Woman's Choice dietary supplement in the United States. This letter is intended to replace our August 4, 1998 notification letter to the FDA advising the agency of statements being made for the Woman's Choice product. It contains a revision of certain statements made in our August 4 notification letter, and reflects the Company's response to the FDA's comments on those statements, as set forth by the agency in its August 18, 1998 "courtesy" letter to us.

With all due respect, Herbalife disagrees with the view expressed in the agency's August 18 letter, which characterized the naturally-occurring process of menopause as a "disease". We respectfully request that the agency share with us the scientific basis supporting such an opinion, an opinion which we believe runs directly counter to the prevalent view of medical experts - which is that menopause is a natural condition which occurs as women age. Despite our disagreement with the agency's views on this subject, Herbalife has nonetheless revised the language that it will use to promote Woman's Choice in our product literature.

Woman's Choice dietary supplement is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

LABEL

Suggested Serving: One or two tablets per day.

Woman's Choice contains a special blend of isoflavones from Red Clover, Soy and Kudzu plus Black Cohosh which helps promote hormone balance in women.

PRODUCT LITERATURE

As women approach age 35 and beyond, they experience a variety of indications, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during time of life. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover Extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

97S - 0162

LET 3354

Also see dockets 97S-0163 + 0162

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December 30, 1998
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- Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance.

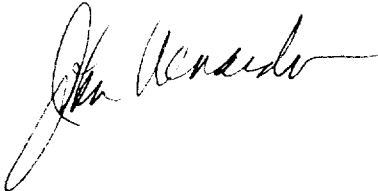
Product labeling prominently bears the required boxed statement, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

Finally, we look forward to receiving at your earliest convenience the information requested above that supports the agency's view, stated in the August 18 letter, that menopause is somehow a disease rather than a naturally-occurring process.

Please do not hesitate to advise should you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Henderson", written in a cursive style.

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Herbalife products are available only through Herbalife Independent Distributors.

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Woman's Choice

Dietary Supplement
for Women

30 TABLETS

EACH TABLET PROVIDES

RED CLOVER EXTRACT (1%)	50 MG
SOY ISOFLAVONES EXTRACT (40%)	30 MG
KUDZU EXTRACT (40%)	30 MG
BLACK COHOSH EXTRACT (8%)	10 MG
BIO-ABSORPTION COMPLEX-5	23 MG
LECITHIN, ASCORBYL PALMITATE, PLANT CELLULOSE, ENZYME, CINNAMON POWDER AND BIOPERINE® (BLACK PEPPER EXTRACT)	

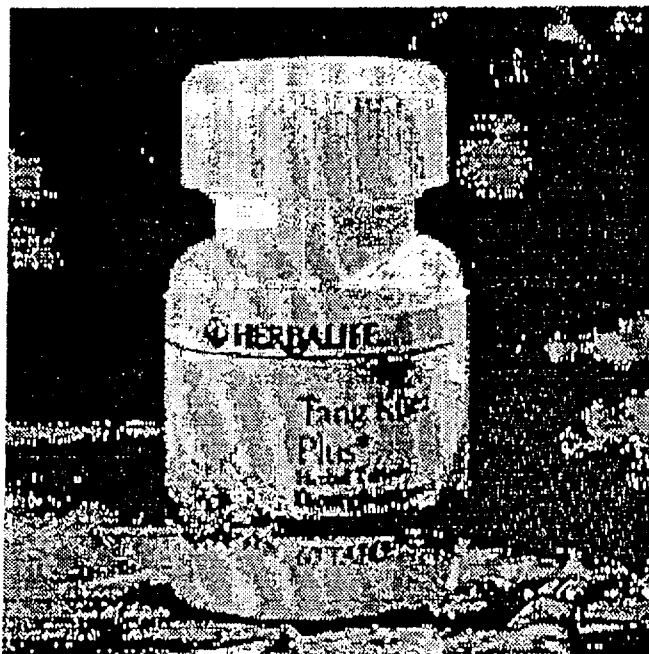
30 day money back guarantee.

FORMULATED EXCLUSIVELY FOR:
HERBALIFE INTERNATIONAL OF AMERICA, INC.
LOS ANGELES, CA 90080-0210, U.S.A.

MADE IN U.S.A.



Special Supplements For Women



Tang Kuei Plus*

Superior nutritional tonic especially for women.

Tang Kuei has been used for centuries in China as a general nutritional tonic, particularly beneficial for women. The root of the plant is preferred because it is a rich source of B vitamins, Calcium, Iron, Magnesium and essential oils. In the Chinese system, Tang Kuei is considered a "superior herb" that can be taken on a daily basis and is often added to soups and broths to increase the nutritional value of these dishes.

- Specially formulated to normalize the challenges associated with a woman's menstrual cycle.
- Includes the additional benefit of Chamomile. This multipurpose plant was used by the Ancient Greeks and was considered a sacred herb by the early Anglo-Saxons.
- Includes Calcium and Magnesium, as well as Vitamin A.

#1014 (case of 12)

#0003 (HAP or unit) \$12.50

Woman's Choice

Dietary supplement for women.

As women approach age 35 and beyond, they experience a variety of indications, some of which are related to declining estrogen levels. This normal occurrence often causes discomfort, including sleep disturbance. Many studies suggest that isoflavones may help women meet nutritional needs during this time of life. Isoflavones have a chemical structure similar to the body's natural estrogen, which may account for these effects. Additionally, isoflavones help maintain a healthy cholesterol level and preliminary studies show that soy isoflavones may increase bone mass. Woman's Choice is rich in natural sources of isoflavones, including Black Cohosh, Red Clover extract and Kudzu Root. It also contains antioxidants that assist the body's defense against the effects of free radicals.

o Contains a special blend of isoflavones from Red Clover, Soy and Kudzu, along with antioxidant-rich Black Cohosh, that may promote hormone balance.

#3015 (case of 12)

#0166 (HAP or unit) \$22.90

